

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. BOX 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-----------------|--------------------------|---------------------|------------------|
| 10/623,751 | 07/22/2003 | Rintaro Yamada | 2870-0263P | 7683 |
| 2292 | 7590 04/28/2005 | | EXAMINER | |
| BIRCH STE | WART KOLASCH & | DAVIS, ZINNA NORTHINGTON | | |
| PO BOX 747 | | | | |
| FALLS CHURCH, VA 22040-0747 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | | |

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|-----------------------------------|--|--|--|--|
| Office Action Comment | 10/623,751 | YAMADA ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Zinna Northington Davis | 1625 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | |
| 1) Responsive to communication(s) filed on | <u>.</u> . | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ Thi | s action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | |
| 4)⊠ Claim(s) 1-53 is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6) Claim(s) is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) 1-53 are subject to restriction and/or election requirement. Application Papers | | | | | |
| 9) The specification is objected to by the Examiner | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents | have been received. | | | | |
| 2. Certified copies of the priority documents | have been received in Application | on No | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal P | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | |
| S. Patent and Trademark Office | | | | | |

Application/Control Number: 10/623,751

Art Unit: 1625

Election/Restrictions

Page 2

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-33 and 38-153 drawn to a compound of formula (1).
- II. Claim 34, drawn to a medicament used for prophylactic and/or therapeutic treatment of glaucoma using a compound of formula (1).
- III. Claim 35, drawn to a medicament used for prophylactic and/or therapeutic treatment of bronchial asthma and/or chronic obstructive pulmonary disease using a compound of formula (1).
- IV. Claim 36, drawn to an inhibitor of the phosphorylation of myosin regulatory light chain, which comprises a compound of formula (1).
- V. Claim 37, drawn to an inhibitor of the Rho/Rho kinase pathway,
 which comprises a compound of formula (1).
- 2. Inventions I-V are related as product claims. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP \Rightarrow 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. For instance, see the claims 34-37.
- 3. This application contains claims directed to the following patentably distinct species of the claimed invention: R^1 , R^2 and R^3 .

The ring system and radicals within the definition of R¹, R² and R³ are diverse in scope. A prior art reference which anticipates one member of R¹ such as halogen under

Application/Control Number: 10/623,751

Art Unit: 1625

35 U.S.C. 102 would not render obvious another member such as −S(O)₂methyl under 35 U.S.C. 103. Accordingly, the ring systems and the radicals are independent and patentably distinct.

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-53 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Application/Control Number: 10/623,751 Page 4

Art Unit: 1625

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

- 6. The examiner has required restriction between product and process claims.

 Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

 Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
- 7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

Art Unit: 1625

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

- 8. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.
- 9. A telephone call was made to Mr. John Bailey on April 18, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.
- 10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682. The examiner can normally be reached on M-F.

Application/Control Number: 10/623,751 Page 6

Art Unit: 1625

13. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to telephone number is 571-272-1600.

Zinna Northington Davis
Primary Examiner
Art Unit 1625

znd April 22, 2005